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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,010	02/02/2001	Gregory Bruce Wilson	0179/61248-A/JPW/BJA	7419

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EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/776,010	WILSON ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,33,36-40,42,43,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,33,36-40,42,43,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on 09/29/06. Claims 32-33, 36-40, 42-43, 46-47 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

1. Claims 32-33, 36-40, 42-43 and 46-47 are still rejected under 35 U.S.C. 103(a) as being unpatentable over by Wilson et al. (Patent No. 4,816, 563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86) on the same ground as stated in the previous office action.

2. In response, Applicants traverse the rejection by only arguing that Ablashi et al. do not isolate and use HHV-6A specific and HHV-6B specific transfer factor (TF) because the TF is isolated from the mice immunized with HHV-6 alone with other viruses of EBV and CMV. Applicants also submit the Ablashi et al. did not identify that the causative agents of CFS is HHV-6 and they only teach the active a chronic viral infection of EBV and/or HHV-6 could play a role. Therefore, Applicants assert that Ablashi et al. in combination with Wilson et al. do not teach or suggest the HHV-6 A and HHV-6B TF.

3. Applicants' argument has been fully considered; however, it is not found persuasive. Because applicant's argument is against the reference individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

4. In the instant case, the rejection is made by Wilson et al. (Patent No. 4,816, 563) in view of Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86). Wilson et al. clearly teach variety approaches for producing and purifying antigen specific TFs, including human herpesvirus specific TF (See example 2 and claims 1-20) from milk or the colostrums of an infected female mammal, wherein the cells, casein and fat or other unwanted materials are separated from the purified TF (See entire document, e.g. Column 2-3, examples 1-6 and claims 1-20). While

Wilson et al. do not explicitly teach to use HHV-6 for generating TF, they clearly teach a method for generating antigen specific TF that is applicable for any ordinary skill in the art. Apparently, this is applicants' admitted fact since there is not any argument about this.

5. The reference by Ablashi et al. teaches why use of HHV-6 has a significantly value while Ablashi et al. cite in the reference that causative agent of CFS is not identified. Ablashi et al. clearly state in the reference that the causative agent of CFS are not yet in deified. However, it is probably that active chronic viral infection, such as EBV and/or HHV-6, could play a role in the etiopathology of the syndromes. But besides the viral gents, other factors could share a responsibility in the pathogenesis of CFS. Whatever factors were responsible for the outset of the CFS symptomatology in patient 2, the virus specific TF seems to have suppressed effect, thereby improving the patient's clinical condition (Please see page 84, last paragraph). In abstract, Ablashi et al. also clearly concluded that HHV-6 infection is related to the development of CFS, and administration HHV-6 specific TF inhibit the HHV-6 infection and improve the clinic manifestation of CFS. Therefore, HHV-6 specific TF may be of significant value in controlling HHV-6 infection and related diseases (Please see page 81).

6. From this content, the valuable information taught by Ablashi et al is not whether the causative agent of HHV-6 infection is identified as the only one causative agent for the CFS, it is that the HHV-6 specific TF exhibits a significant therapeutic value in turn of suppressing the clinical symptoms or complication associated with HHV-6 infection or its related disease. Therefore, Ablashi et al. clearly teaches a motivation for any ordinary skill in the art to make HHV-6 specific TF. To this context, the claimed invention as a whole is still considered as prima facie obvious absence unexpected results.

7. Claims 32, 38, 42 are still rejected under 35 U.S.C. 103(a) as being unpatentable over by Advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p 29) in view of Advertisement by Chisolm Biological Laboratory in Positive Health News, Fall, 1997, p. 27) and EP (0 143,445).

8. Applicants traverse the rejection and submit that HHV-6 A or HHV-6 B specific TF was ever made by the disclosure of Positive Health News Report, No. 17 Fall Issue 1998. Applicants note that the News Report No. 17 discusses a proposed product named "Immunfactor6"which

may contain transfer factors specific for various subsets and refers to HHV6A. Applicants further note that News Report No. 15 discusses "Immunfactor," which is directed against 12 viruses including HHV6. EP 0143445 discusses a method of creating transfer factor from colostrums of immunized bovid. Pertinently, the cited advertisements in combination with EP 0143445 teach, at most, a non-specific transfer factor product raised for multiple viruses. Combined, they do not teach the elements of (i) a fluid consisting of a colostrums of a human herpesvirus-6A-immunized lactating bovid, wherein the colostrums has removed from it cells, casein and fat, (ii) a fluid consisting of a colostrums of a human herpesvirus-6A-immunized lactating bovid, wherein the colostrums has removed from it cells, casein and fat or (iii) a method for treating CFS using such compositions.

9. Applicants' argument has bee fully considered; the rejection of claims read on product of colostrums comprising HHV-6B specific TF and method for using said product has been removed because the cited references do not particularly teach and suggest to make the HHV-6B specific TF.

10. However, the rejection over other claims that are directed to colostrums product comprising HHV-6A specific TF is still maintained for the reasons set forth below:

11. An obvious rejection under 35 U.S.C. 103(a) is not based on a cited references that teaches an identical subject matter disclosed or described as set forth in section 102 of this title, it is based on whether the difference between the claimed subject matter and prior art as a whole would have been obvious at the time the invention was made to a person having an ordinary skill in the art to which said subject matter pertains.

12. In the instant case, the examiner has noticed that the transfer factor advertised by the News Report No. 15 is multivalent. However, the News Report No. 17 clearly teaches that the HHV-6A specific TF was already under development at that time of 1989 (See page 1 of the Report). For example, it cites on page 22 " More transfer factors products that are specific for the condition like MAC, Toxoplasmosis and HHV-6A are urgently needed. Most of the drugs used for treating theses conditions have serious side effects and often do not complete clear the infection. … ANIMUNE is developing transfer factors for HIV, HHV6A, HHV-6B, EBV, HHV-8 and hepatitis A, B and C. We wish ANIMUNE success in the development of their transfer factor products, especially the one for HHV-6A. …."(See page 22).

13. EP (0 143,445) is the Foreign priority document of the US patent No. 4,816, 563, and is has the same disclosure described above. For example, it clearly teaches variety approaches for producing and purifying antigen specific TFs, including human herpesvirus specific TF from milk or the variety approaches for producing and purifying antigen specific TFs, including human herpesvirus specific TF (See example 2 and claims 1-20) from milk or the colostrums of an infected female mammal, wherein the cells, casein and fat or other unwanted materials are separated from the purified TF (See entire document, e.g. Column 2-3, examples 1-6 and claims 1-20).colostrums of an infected female mammal free of cells or casein or fat (See entire document, and claims 1-20).

14. To this context, the combination of references obviously teaches and suggests for an artisan with an ordinary skill in the art the motivation and method for making the HHV-6A specific TF. Therefore, the rejected claims as a whole is still considered as prima facie obvious absence unexpected results. The rejection is maintained.

Conclusion

No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li
11/30/2006

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